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1632 #

Enz-57(CIP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Brown et al

Serial No. 10/042,711

Filed: December 12, 2001

Title: BIOLOGICAL MODELS CAPABLE OF EXHIBITING  
DISEASE MANIFESTATIONS AND USEFUL FOR  
DEVELOPING THERAPEUTIC DRUGS,  
DIAGNOSTIC PRODUCTS AND THERAPEUTIC  
OR DIAGNOSTIC PROCEDURES, METHODS OF  
USING SAME, AND CELLS, TISSUES AND  
ORGANS DERIVED THEREFROM

Group Art Unit: 1632

Examiner: Anne Marie Falk

527 Madison Avenue, 9<sup>th</sup> Floor  
New York, New York 10022  
April 2, 2004

**FILED VIA EXPRESS MAIL**

Mail Stop No-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§1.56 & 1.97-1.98**

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.97-1.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following twenty-two (22) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

04/07/2004 SDENB0B1 00000066 051135 10042711  
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Enz-57(CIP)

Brown, et al

Serial No.: 10/042,711

Filed: December 12, 2001

Page 2 [Information Disclosure Statement – April 2, 2004]



### EXPRESS MAIL CERTIFICATE

"Express Mail" Label No.: EL833441807US

Deposit Date: April 2, 2004

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Ronald C. Fedus  
Reg. No. 32,567

APR 2 2004  
Date

1. Brown, et al., U.S. Patent Application No. 08/876,635, filed on June 16, 1997 published on July 5, 2001 as US-2001-0007153-A1 [Exhibit 1];
2. Liu, D., et al., "Stable Human Immunodeficiency Virus Type 1 (HIV-1) Resistance in Transformed CD4+ Monocytic Cells Treated with Multitargeting HIV-1 Antisense Sequences Incorporated into U1 snRNA," J. Virol. 71:4079-4085 (1997) [Exhibit 2];
3. Roy-Chowdhury, et al., U.S. Patent Application No. 08/808,629, filed on February 28, 1997; specification subsequently published in continuing U.S. Patent Application No. 10/377,628. filed March 4, 2003 and published as US-2004-0022768-A1 [Exhibit 3];
4. Shibata, R., et al., "Early replication block of human immunodeficiency virus type 1 in monkey cells," J. Gen. Virol. 76:2723-2730 (1995) [Exhibit 4];
5. Walter, E., et al., "Hepatitis B Virus Infection of Tupaia Hepatocytes *In Vitro* and *In Vivo*," Hepatology 24:1-5 (1996) [Exhibit 5];
6. Yan, R.Q., et al., "Human hepatitis B virus and hepatocellular carcinoma I. Experimental infection of tree shrews with hepatitis B virus," J. Cancer Res. Clin. Oncol. 122:283-288 (1996) [Exhibit 6];
7. Yan, R.Q., et al., "Human hepatitis B virus and hepatocellular carcinoma II. Experimental induction of hepatocellular carcinoma in tree shrews exposed to Hepatitis B virus and aflatoxin B1," J. Cancer Res. Clin. Oncol. 122:289-295 (1996) [Exhibit 7]
8. Bowling, W.M., et al., "Portal Branch Occlusion Safely Facilitates *In Vivo* Retroviral Vector Transduction of Rat Liver," Human Gene Therapy 7:2113-2121 (1996) [Exhibit 8];
9. Engelhardt, J., et al., "Direct gene transfer of human CFTR into human bronchial epithelia of xenografts with E1-deleted adenoviruses," Nature Genetics 4:27-33 (1993) [Exhibit 6];
10. Kim, T.S., et al., "Immunity to B16 melanoma in mice immunized with IL-2-secreting allogeneic mouse fibroblasts expressing melanoma-associated antigens," Int. J. Cancer 51:283-289 (1992) [Exhibit 10];

11. McCune, J.M., et al., "The SCID-hu Mouse: Murine Model for the Analysis of Human Hematolymphoid Differentiation and Function," Science 241:1632-1639 (1988) [Exhibit 11];
12. Orkin, S.H., and Motulsky, A.G., "Report and recommendations of the panel to assess the NIH investment in research on gene therapy," NIH Ad-Hoc Committee Report, December 7, 1995 [Exhibit 12];
13. Reisner, Y., United States Patent No. 5,709,843, filed November 23, 1994 [Exhibit 13];
14. Rhim, J.A., et al., "Complete reconstitution of mouse liver with xenogeneic hepatocytes," Proc. Natl. Acad. Sci. USA 92:4942-4946 (1995) [Exhibit 14];
15. Weber, M., et al., "Adenoviral Transfection of Isolated Pancreatic Islets: A Study of Programmed Cell Death (Apoptosis) and Islet Function," J. Surgical Research 69:23-32 (1997) [Exhibit 15];
16. Wilson, J.M., and Mulligan, R.C., United States Patent No. 5,580,776, filed February 25, 1994 [Exhibit 16];
17. Agy, M.B., et al., "Infection of *Macaca nemestrina* by Human Immunodeficiency Virus Type-1," Science 257:103-106 (1992) [Exhibit 17];
18. Barnett, S.W., et al., "An AIDS-Like Condition Induced in Baboons by HIV-2," Science 266:642-646 (1994) [Exhibit 18];
19. Kuby, J., et al., Immunology, 2<sup>nd</sup> Edition, pp. 496-497, W.H. Freeman and Co., New York (1994) [Exhibit 19];
20. Lewis, A.D., et al., "Developing animal models for AIDS research – progress and problems," Trends in Biotechnology 13:142-150 (1995) [Exhibit 20];
21. Mosier, D.E., et al., "Human Immunodeficiency Virus Infection of Human-PBL-SCID Mice," Science 251:791-794 (1991) [Exhibit 21];
22. Namikawa, R., et al., "Infection of the SCID-hu Mouse by HIV-1," Science 242:1684-1686 (1988) [Exhibit 22];

The first seven (7) foregoing references (numbers 1-7) were cited in the specification of the instant application.

The next nine (9) foregoing references (numbers 8-16) were cited in an Office Action dated July 7, 1998 issued in relation to an earlier parent application, U.S. Patent Application No. 08/876,635, filed June 16, 1997.

The following six (6) foregoing references (numbers 17-22) were cited in an Office Action dated September 12, 2000 issued in relation to the parent application, U.S. Patent Application No. 09/356,293, filed July 16, 1999.

A completed Form PTO-1449 listing the 22 above-submitted documents is also attached hereto as Exhibit 23.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith, which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant

Brown, et al  
Serial No.: 10/042,711  
Filed: December 12, 2001  
Page 6 [Information Disclosure Statement – April 2, 2004]

application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is \$180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



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Natalie Bogdanos  
Registration No. 51,480  
Attorneys for Applicants

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Brown et al

Serial No. 10/042,711

Group Art Unit: 1632

Filed: December 12, 2001

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Title: BIOLOGICAL MODELS CAPABLE OF EXHIBITING DISEASE MANIFESTATIONS AND USEFUL FOR DEVELOPING THERAPEUTIC DRUGS, DIAGNOSTIC PRODUCTS AND THERAPEUTIC OR DIAGNOSTIC PROCEDURES, METHODS OF USING SAME, AND CELLS, TISSUES AND ORGANS DERIVED THEREFROM

**TRANSMITTAL  
INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

EXPRESS MAIL CERTIFICATE	
"Express Mail" Label No.:	<u>EL833441807US</u>
Deposit Date:	<u>April 2, 2004</u>
I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
 Ronald C. Fedus Reg. Exhibit 32,567	<u>APR 2 2004</u> Date

Enz-57(CIP)

1. ☐ For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
2. ☐ For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
3. ☐ Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior ☐ Divisional or ☐ Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_.
4. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:
  - ☐ 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.
  - ☐ 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application.
  - ☐ 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.
5. ☐ No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.
6. ☒ A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):
  - ☐ A check in the amount of \$180.00 is enclosed in payment of the fee.



☒ Charge the fee to Deposit Account No. 05-1135, Order No. **Enz-57(CIP)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:
- a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and
  - b. the attached petition requesting consideration of this Information Disclosure Statement; and
  - c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.
8. ☐ A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:
- a. ☐ 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;
  - b. ☐ 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.
  - c. ☐ The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.
9. ☐ I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

**Enz-57(CIP)**

10. ☐ A check in the amount of \$180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

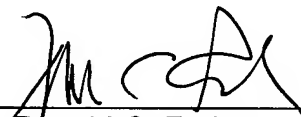
☒ Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **Enz-57(CIP)**. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: April 2, 2004

By: \_\_\_\_\_



Ronald C. Fedus

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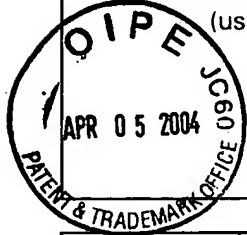
**Enz-57(CIP)**

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

## INFORMATION DISCLOSURE CITATION

(use several sheets if necessary)

Atty. Docket No.  
ENZ-57(CIP)

Serial No. 10/042,711

Applicants: Brown, et al

Filed: Dec. 12, 2001

Group: 1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO- PRIATE
	20 01	0	0	0	7	1	5	3	6/16/97	Brown, et al.	A1		
	20 04	0	0	2	2	7	6	8	3/4/03	Roy-Chowdhury, et al.	A1		
		5	7	0	9	8	4	3	11/23/94	Reisner, Y.			
		5	5	8	0	7	7	6	2/25/94	Wilson, et al.			

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	NAME	CLASS	SUB CLASS	TRAN- SLATION YES NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Liu, D., et al., "Stable Human Immunodeficiency Virus Type 1 (HIV-1) Resistance in Transformed CD4+ Monocytic Cells Treated with Multitargeting HIV-1 Antisense Sequences Incorporated into U1 snRNA," J. Virol. 71:4079-4085 (1997)
		Shibata, R., et al., "Early replication block of human immunodeficiency virus type 1 in monkey cells," J. Gen. Virol. 76:2723-2730 (1995)
		Walter, E., et al., "Hepatitis B Virus Infection of Tupaia Hepatocytes <i>In Vitro</i> and <i>In Vivo</i> ," Hepatology 24:1-5 (1996)
		Yan, R.Q., et al., "Human hepatitis B virus and hepatocellular carcinoma I. Experimental infection of tree shrews with hepatitis B virus," J. Cancer Res. Clin. Oncol. 122:283-288 (1996)
		Yan, R.Q., et al., "Human hepatitis B virus and hepatocellular carcinoma II. Experimental induction of hepatocellular carcinoma in tree shrews exposed to Hepatitis B virus and aflatoxin B1," J. Cancer Res. Clin. Oncol. 122:289-295 (1996)
		Bowling, W.M., et al., "Portal Branch Occlusion Safely Facilitates <i>In Vivo</i> Retroviral Vector Transduction of Rat Liver," Human Gene Therapy 7:2113-2121 (1996)
		Engelhardt, J., et al., "Direct gene transfer of human CFTR into human bronchial epithelia of xenografts with E1-deleted adenoviruses," Nature Genetics 4:27-33 (1993)

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce

(REV. 8-83) Patent and Trademark Office

Atty. Docket No.  
ENZ-57(CIP)

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	Kim, T.S., et al., "Immunity to B16 melanoma in mice immunized with IL-2-secreting allogeneic mouse fibroblasts expressing melanoma-associated antigens," <u>Int. J. Cancer</u> 51:283-289 (1992)
	McCune, J.M., et al., "The SCID-hu Mouse: Murine Model for the Analysis of Human Hematolymphoid Differentiation and Function," <u>Science</u> 241:1632-1639 (1988)
	Orkin, S.H., and Motulsky, A.G., "Report and recommendations of the panel to assess the NIH investment in research on gene therapy," NIH Ad-Hoc Committee Report, Dec. 7, 1995
	Rhim, J.A., et al., "Complete reconstitution of mouse liver with xenogeneic hepatocytes," <u>Proc. Natl. Acad. Sci. USA</u> 92:4942-4946 (1995)
	Weber, M., et al., "Adenoviral Transfection of Isolated Pancreatic Islets: A Study of Programmed Cell Death (Apoptosis) and Islet Function," <u>J. Surgical Res.</u> 69:23-32 (1997)
	Agy, M.B., et al., "Infection of <i>Macaca nemestrina</i> by Human Immunodeficiency Virus Type-1," <u>Science</u> 257:103-106 (1992)
	Barnett, S.W., et al., "An AIDS-Like Condition Induced in Baboons by HIV-2," <u>Science</u> 266:642-646 (1994)
	Kuby, J., et al., <u>Immunology</u> , 2 <sup>nd</sup> Edition, pp. 496-497, W.H. Freeman and Co., NY (1994)
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\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.